IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

LINDA MESSICK,

Plaintiff,

v.

NOVARTIS PHARMACEUTICALS CORP.,

Defendant.

_____/

No. CV 12-00693 SI

ORDER GRANTING DEFENDANT'S *DAUBERT* MOTION TO EXCLUDE CAUSATION TESTIMONY AND MOTION FOR SUMMARY JUDGMENT

In June 2011, while this action was pending in the Middle District of Tennessee for pretrial proceedings as part of MDL No. 1760 (*In re Aredia and Zometa Products Liability Litigation*), defendant Novartis Pharmaceuticals Corp. filed a *Daubert* motion to exclude specific causation testimony of plaintiff Linda Messick's retained expert, Dr. Richard Jackson, and plaintiff's non-retained experts, Drs. Gary Cecchi, Herbert Fawcett, Pritchard Lam, Matthew Liautaud, Nasser Said-Al-Naief, and Sol Silverman; and also a motion for summary judgment. Those motions were briefed but not decided in the MDL proceeding. Rather, in October 2011 this action was remanded to the Eastern District of North Carolina, where it had originally been filed. Thereafter, on plaintiff's unopposed motion to transfer, the action was transferred from the Eastern District of North Carolina to this District in February, 2012.

On November 8, 2012, this Court heard argument on defendant's motions. Having considered the parties' arguments, the Court hereby GRANTS defendant's *Daubert* motion as to Drs. Lam, Silverman, and Jackson. It also GRANTS defendant's motion for summary judgment, for the reasons set forth below.

BACKGROUND

Plaintiff Linda Messick was diagnosed with breast cancer in August 2000. Pl.'s Response to Def.'s Statement of Undisputed Facts in Supp. of Summ. J. ("Pl.'s Resp. to Def.'s SUF") ¶ 11. She received radiation therapy and several medications, and in April 2002, she was diagnosed with osteoporosis. *Id.* ¶ 16. From May 7, 2002 to November 14, 2002, Ms. Messick was treated with Zometa therapy, and from December 12, 2002 to June 10, 2004, she was treated with Aredia therapy; both therapies were prescribed by Dr. Cecchi, her oncologist. *Id.* ¶ 17-19.

During and after her Zometa and Aredia treatments, Ms. Messick visited the dentist for a variety of conditions. She had dental caries; restorative dental work requiring fillings, root canals, crowns, extractions and bridge adjustments; mobility in her lower right teeth; and moderate bone loss on tooth #28. Def.'s Statement of Undisputed Facts ("Def.'s SUF") ¶¶ 27, 28. Dr. Lam extracted tooth # 29 in 2002, tooth #20 in 2003, and tooth #28 in 2004. *Id.* Ex. 59 ("Lam Dep. II") 49:1-16, 56:1-12; Vecchione Decl., Ex. 6 ("Lam Dep. III") 51:17-22. Additionally, Ms. Messick suffered a hydrochloric acid accident which occurred during a root canal procedure. Lam Dep. III 55:1-3. In August 2002 and November 2003, Ms. Messick was diagnosed with periodontal disease. Def.'s SUF ¶¶ 23-27.

On July 17, 2004, Dr. Cecchi recorded that Ms. Messick's "results improved" and discontinued her Aredia treatment, although the parties dispute whether the "results" referred to Ms. Messick's bone density. *Id.* ¶ 20. The parties dispute whether the Aredia and Zometa therapy was used to treat Ms. Messick's osteoporosis, which is an off-label use. *Id.* ¶ 17-18. In October 2005, Ms. Messick developed exposed bone in her mouth, which healed completely by October 2008, *id.* ¶ 33; plaintiff characterizes this as osteonecrosis of the jaw ("ONJ").

Novartis is a pharmaceutical company engaging in marketing, distributing, promoting, testing, labeling, and selling the drugs Aredia and Zometa. Second Amended Complaint ("SAC") ¶ 5. Aredia and Zometa are bisphosphonates prescribed for the management of metastatic disease to the bone and other bone diseases and conditions. *Id.* ¶ 7. On October 31, 1991, the FDA approved Aredia for the treatment of hypercalcemia of malignancy and approved the labeling. Pl.'s Resp. to Def.'s SUF ¶ 1. In September 1995, the FDA approved Aredia for other indications, including osteolytic bone metastases related to breast cancer. *Id.* ¶ 2. On August 20, 2001, the FDA approved Zometa for hypercalcemia of

malignancy and approved the labeling. *Id.* ¶ 3. In February 2002, the FDA approved Zometa for multiple myeloma and bone metastases from solid tumors. *Id.* ¶ 4.

On September 26, 2003, Novartis notified the FDA by letter that it was voluntarily revising the Adverse Reactions section of the Aredia and Zometa labeling to reflect information from recent reports of osteonecrosis of the jaw associated with the use of intravenous bisphosphonates. *Id.* ¶ 43. The same month Dr. Marx published an article discussing the prevalence of ONJ in patients being treated with Aredia and Zometa. *Id.* ¶ 43. The parties dispute when the public at large learned of the labeling change. *Id.*

On March 4, 2008, plaintiff filed a Second Amended Complaint alleging that Aredia and Zometa caused her ONJ, and that Novartis knew or should have known that bisphosphonates cause changes to patients' upper and lower jaws that can progress to jaw necrosis and osteomyelitis. SAC ¶ 12. Plaintiff alleges that in 2002, following physicians' reports that patients taking Aredia or Zometa reported severe complications and sometimes losses of their jaws, Novartis failed to implement studies regarding the risk of ONJ relative to Zometa and Aredia; and that Novartis did not notify physicians of the risk of ONJ until September 2004 and dental professionals until May 2005. *Id.* ¶ 14-15.

LEGAL STANDARD

I. Motion to Exclude Plaintiff's Expert Witnesses

Federal Rule of Evidence 702 provides that expert testimony based upon knowledge, skill, experience, training, or education is admissible if "(a) scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case." Fed. R. Evid. 702.

The district court is charged with making the gateway determinations of whether the expert testimony is reliable and relevant. *See Barabin v. AstenJohnson, Inc.*, 10-36142, 2012 WL 5669685, at *4 (9th Cir. Nov. 16, 2012) (reversing a district court for not making reliability or relevance findings, and admitting the testimony "[i]n the interest of allowing each party to try its case to the jury"). As a

guide for assessing the scientific validity of expert testimony under the reliability prong of Rule 702, the Supreme Court provided a nonexhaustive list of factors that courts may consider: (1) whether the theory or technique is generally accepted within a relevant scientific community, (2) whether the theory or technique has been subjected to peer review and publication, (3) the known or potential rate of error, and (4) whether the theory or technique can be tested. *Daubert v. Merrell Dow Pharms., Inc*., 509 U.S. 579, 593-94 (1993); *see also Kumho Tire Co. v. Carmichael*, 526 U.S. 137 (1999). The Ninth Circuit also has indicated that independent research, rather than research conducted for the purposes of litigation, carries with it the indicia of reliability. *See Daubert v. Merrell Dow Pharms., Inc*. (*Daubert II*), 43 F.3d 1311, 1317 (9th Cir. 1995).

If the testimony is not based on "pre-litigation" research or if the expert's research has not been subjected to peer review, then the expert must explain precisely how he went about reaching his conclusions and point to some objective source – a learned treatise, the policy statement of a professional association, a published article in a reputable scientific journal or the like – to show that he has followed the scientific method, as it is practiced by (at least) a recognized minority of scientists in his field. *Id*. at 1318-19 (*citing United States v. Rincon*, 28 F.3d 921, 924 (9th Cir. 1994)); *see also Lust v. Merrell Dow Pharms., Inc*., 89 F.3d 594, 597 (9th Cir. 1996). The proponent of the evidence must prove its admissibility by a preponderance of proof. *See Daubert*, 509 U.S. at 592 n.10.

II. Motion for Summary Judgment

Summary adjudication is proper when "the pleadings, depositions, answers to interrogatories, and admissions on file, together with affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c).

In a motion for summary judgment, "[if] the moving party for summary judgment meets its initial burden of identifying for the court those portions of the materials on file that it believes demonstrate the absence of any genuine issues of material fact, the burden of production then shifts so that "the non-moving party must set forth, by affidavit or as otherwise provided in Rule 56, 'specific facts showing that there is a genuine issue for trial.'" *See T.W. Elec. Service, Inc. v. Pacific Elec.*

Contractors Ass'n, 809 F.2d 626, 630 (9th Cir. 1987) (citing *Celotex Corp. v. Catrett*, 477 U.S. 317 (1986)).

In judging evidence at the summary judgment stage, the Court does not make credibility determinations or weigh conflicting evidence, and draws all inferences in the light most favorable to the nonmoving party. *See T.W. Electric*, 809 F.2d at 630-31 (citing *Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574 (1986)); *Ting v. United States*, 927 F.2d 1504, 1509 (9th Cir. 1991). The evidence presented by the parties must be admissible. Fed. R. Civ. P. 56(e). Conclusory, speculative testimony in affidavits and moving papers is insufficient to raise genuine issues of fact and defeat summary judgment. *See Falls Riverway Realty, Inc. v. City of Niagara Falls*, 754 F.2d 49 (2d Cir. 1985); *Thornhill Publ'g Co., Inc. v. GTE Corp.*, 594 F.2d 730, 738 (9th Cir. 1979).

DISCUSSION

I. Motion to Exclude Plaintiff's Expert Witnesses

In support of her suit, plaintiff Messick proffers her treating physicians and retained expert Dr. Jackson as witnesses who will testify that Aredia and Zometa caused her ONJ. Defendant moves to exclude the specific causation testimony of these expert witnesses. Because plaintiff conceded that Drs. Cecchi, Fawcett, Liautaud, and Said-Al-Naief do not offer specific causation testimony, Pl.'s Opp. at 9, 10, 13, their testimony does not fall within the scope of this *Daubert* motion. Therefore, the Court only considers whether the specific causation testimony of Drs. Jackson, Lam, and Silverman should be excluded.

A. Dr. Jackson

Dr. Jackson completed his oral and maxillofacial surgery residency in 1982 and became Board Certified in oral maxillofacial surgery in 1984. Mem. in Supp. of Def.'s Mot. to Exclude Causation Testimony of Pl.'s Experts, Ex. 2 ("Independent Medical Examination of Linda Messick" or "IME"). Dr. Jackson has not been involved in any lectures on ONJ, has not conducted research on bisphosphonates or ONJ, and has not been part of any clinical studies in the past seven years. Mem. in Supp. of Mot. to Exclude Causation Testimony of Pl.'s Experts, Ex. 3 ("Jackson Dep. I") 20:14-19,

21:2-14. However, he has had "extensive experience" with ONJ in the past and present, and is the primary oral and maxillofacial surgeon managing ONJ in the Sacramento area. IME. Starting in 2003, he "began to see many more cases of osteonecrosis" in patients who had not received radiation therapy to the jaw. *Id.* After consulting six medical articles published in *Annals of Internal Medicine*; *Journal of Oral Maxillofacial Surgery*; *Oral Surgery, Oral Medicine, Oral Pathology, Oral Radiology and Endodontology*; and by the American Association of Oral Maxillofacial Surgeons ("AAOMS"), Dr. Jackson opined that the bisphosphonates in intravenous and oral form were the etiologic factor of ONJ, and not radiation: "it is my opinion that bisphosphonates have in the past and present always shown a propensity to cause jaw necrosis in patients." *Id.*

Dr. Jackson examined Ms. Messick on February 4, 2011, several years after her ONJ resolved. IME. Relying on that physical examination, his review of her medical records, and the statements of her treating physicians, he wrote an expert report setting forth his diagnosis of Ms. Messick's exposed bone. Jackson Dep. I. 102:1-6. In addition, Dr. Jackson obtained a piece of bone that had been extracted from Ms. Messick's mouth in November 2008, which he sent to Dr. Said-Al-Naief for a pathology analysis. *Id.* 26:20-36:14. However, the bone had been stored in a plastic container and had not been preserved, and Dr. Jackson agreed with Dr. Said-Al-Naief's statement that it is not scientifically reliable to do a pathology analysis three years after a sample is obtained, when the sample had not been preserved in any way. Mem. in Supp. of Mot. to Exclude Causation Testimony of Pl.'s Experts, Ex. 4 ("Said Dep.") 60:9-12; Mem. in Supp. of Mot. to Exclude Causation Testimony of Pl.'s Experts, Ex. 5 ("Jackson Dep. II") 221:11-18. In his report, Dr. Jackson listed as risk factors for Ms. Messick's ONJ: use of intravenous Aredia and Zometa, tooth extractions, advanced age (73 years old), Caucasian race, osteopenia, and cortical steroid therapy. IME. He performed a differential diagnosis and found that Ms. Messick met the three criteria defined by the AAOMS for a diagnosis of bisphosphonate-related ONJ ("BRONJ"): (1) she had a past history of Aredia and Zometa use, (2) she had exposed necrotic bone that persisted for more than eight weeks, and (3) she had no history of radiation therapy to the jaws. *Id.* He ruled out alternative diagnoses of radiation-induced osteonecrosis of the jaw because she did not have radiation in her jaw, and non-suppurative osteomyelitis because she did not have any symptoms of infection. *Id.*

(1) Reliability

As an initial matter, a court must determine if a witness has the required expertise under Rule 702(a), whether it be "knowledge, skill, experience, training, or education." Based on Dr. Jackson's medical education, board certification, and his clinical experience as an oral and maxillofacial surgeon treating ONJ, the Court finds that he is qualified under Rule 702(a). However, for other reasons the Court finds that Dr. Jackson's testimony is insufficient to meet the *Daubert* threshold reliability test.

Under the reliability prong of Rule 702, the testimony must reflect scientific knowledge derived from the scientific method. *Daubert II*, 43 F.3d at 1316. In determining whether experts have derived their findings through the scientific method, the Court examines the expert's independent research and reliance on objective sources, such as treatises or published articles in reputable journals. *Id.* at 1318-19. Dr. Jackson's testimony depends both on his clinical experience, and six recent medical publications. These sources, however, these are only reliable for an assertion of general causation, not specific causation in Ms. Messick's case.

As to specific causation, Dr. Jackson tried to rely on a pathology analysis to show that Ms. Messick's ONJ was caused by Aredia and Zometa, but he admitted this was scientifically unreliable, owing to the lack of preservation of the three year-old bone sample. Dr. Jackson performed a differential diagnosis of Ms. Messick's condition, ruling out osteomyelitis, osteoradionecrosis, and osteonecrosis in general, to diagnose her with BRONJ. However, Dr. Jackson identified five other risk factors that contributed to Ms. Messick's BRONJ besides the Aredia and Zometa. Although he asserted that "it just doesn't happen" that a patient with all of Ms. Messick's risk factors but without exposure to bisphosphonates would have developed ONJ, he never explained the scientific basis for this conclusion. Jackson Dep. I 124:20-125:12. Indeed, when asked if there is "any scientifically reliable way for [him] to determine in a patient who has multiple risk factors at one time which of those particular risk factors is causing the underlying necrotic bone in the jaw," he answered "no." Mem. in Supp. of Mot. to Exclude Causation Testimony of Pl.'s Experts, Ex. 6 ("Jackson Dep. III") 116:21-117:1.

The Court finds that Dr. Jackson's opinion that Ms. Messick's ONJ was caused by her

bisphosphonate use, instead of her other risk factors, is not based on reliable scientific methodology. *See also Luttrell v. Novartis Pharms. Corp.*, No. 07-CV-3015 TR, 2012 WL 4513109, at *11 (E.D. Wash. Oct. 1, 2012) (excluding Dr. Jackson's causation testimony in part because he offered no explanation why he ruled out alternative hypotheses of causation beyond "bald assertions" that BRONJ is unique compared to other causes of ONJ).

(2) Relevance

The Court also finds that Dr. Jackson's causation testimony does not meet the relevance requirement of Rule 702. Relevance for purposes of Rule 702 is assessed by looking to the governing substantive standard for causation. *Daubert II*, 43 F.3d at 1320. In this case the governing substantive standard, supplied by California tort law, requires plaintiff to show both general causation (i.e. that the drugs have the capacity to cause the condition at issue) and specific causation (i.e. that the drugs caused the plaintiff's condition): "plaintiffs [] [must] show not merely that [the medication] increased the likelihood of injury, but that it more likely than not caused *their* injuries." *In re Silicon Gel Breast Implants Products Liability Litigation*, 318 F. Supp. 2d 879, 890 (C.D. Cal. 2004) (emphasis in original); *see also Golden v. CH2M Hill Hanford Group, Inc.*, 528 F.3d 681, 683 (9th Cir. 2008); *Daubert II*, 43 F.3d at 1320.

Here, Novartis argues that Dr. Jackson's testimony is not relevant to show that Aredia and Zometa specifically caused Ms. Messick's ONJ. Dr. Jackson's differential diagnosis only determines that Ms. Messick's ONJ is *related* to her bisphosphonate use, and he admits that a diagnosis of BRONJ does not mean that bisphosphonates *caused* her ONJ. *See* Jackson Dep. I 154:11-20 ("Well, the key is not the cause, the key is the support. Bisphosphonates support osteonecrosis, just like oxygen supports fire. So fire is not caused from oxygen, but it certainly is a necessary ingredient."). Although he asserted in a hypothetical that a patient *like* Ms. Messick would not contract ONJ without exposure to bisphosphonates, he never opined that Aredia and Zometa actually caused Ms. Messick's ONJ, and indeed, he stated that there was no scientifically reliable way for him to do so. Thus, Dr. Jackson's testimony is not relevant to determine the specific causation of Ms. Messick's ONJ.

Therefore, because the Court finds that Dr. Jackson's testimony is neither reliable nor relevant

under Rule 702, it GRANTS defendant's motion to exclude Dr. Jackson's testimony.

B. Drs. Lam and Silverman

Dr. Silverman is an oral medicine specialist. Mot. at 9. He saw Ms. Messick from October 5, 2004 to March 31, 2009. Mem. in Supp. of Mot. to Exclude, Ex. 15 ("Silverman Dep.") 18:19-19:2. Dr. Silverman "assumed" Ms. Messick's exposed bone was caused by the history of intravenous bisphosphonate use and Ms. Messick's medical history, *id.* 62:12-15, stating "[t]here was a possibility of an association." *Id.* 95:25-96:6. He did not complete a differential diagnosis to reach that conclusion, nor did he conduct a comprehensive literature search or conduct research relating to ONJ, BRONJ, Aredia, or Zometa, or publish articles relating to BRONJ and ONJ. *Id.* 12:18-25, 52:4-6, 109:3-7.

Dr. Lam is an oral surgeon who treated Ms. Messick from January 17, 1995 to November 20, 2008. Mem. in Supp. of Mot. to Exclude, Ex. 11 ("Lam Dep. I") 18:20-25. Dr. Lam did not make a definitive diagnosis for Ms. Messick's condition, but had a "working diagnosis" or "impression" that Ms. Messick's ONJ was related to her bisphosphonate therapy. *Id.* 92:16-25. In such instances where Dr. Lam does not have his own definitive diagnosis, it has been his habit and custom to refer patients to Dr. Silverman for diagnosis and to defer to him in those circumstances. *Id.* 75:8-15. Dr. Lam looked to Dr. Silverman to provide a more definitive diagnosis for Ms. Messick's condition; Dr. Silverman concurred with Dr. Lam's working diagnosis of osteonecrosis. *Id.* 93:1-11.

The Court finds that because Dr. Silverman merely assumed Ms. Messick's ONJ was bisphosphonate-related and did not rely on scientific methods to determine the cause of Ms. Messick's ONJ, his causation testimony must be excluded. Likewise, because Dr. Lam merely formed an impression and deferred to Dr. Silverman for a definite diagnosis, his causation testimony must be excluded as well. Dr. Silverman's "assumption" and Dr. Lam's "impression" are simply inadequate to satisfy the Ninth Circuit's requirement under Rule 702, that where evidence of pre-litigation research or research subject to peer review is unavailable, the expert must point to an objective source, such as a treatise, policy statement of a professional association, or a published article in a reputable scientific journal. *Daubert II*, 43 F.3d at 1318-19 (testimony inadmissible where expert offered no tests and no testable theory as to causation, only drawing unsupported conclusions and relying on animal studies and

chemical structure analyses). Drs. Lam and Silverman offered only assumptions and impressions. Moreover, neither has shown that Aredia and Zometa more likely than not caused Ms. Messick's injuries, as required under California tort law under the relevance prong of Rule 702. *Id*. at 1320.

The Court finds that neither Dr. Lam nor Dr. Silverman used reliable methods to determine the cause of Ms. Messick's ONJ as required by Rule 702. Therefore, the Court GRANTS defendant's motion to exclude their testimony.

II. Motion for Summary Judgment

Plaintiff alleged six causes of action against Novartis based on her allegation that Aredia and Zometa caused her osteonecrosis of the jaw: (1) strict liability for defective design, manufacture and warning, (2) negligent manufacture, (3) negligent failure to warn, (4) breach of express warranty, (5) breach of implied warranty, and (6) loss of consortium. Certain of the manufacturing and consortium causes of action have been waived. For the remaining causes of action, Novartis argues that summary judgment in its favor is proper for numerous reasons.[1] This Court finds that plaintiff has submitted insufficient evidence to establish causation, and that this failure is dispositive of all her claims.

In a pharmaceutical personal injury action, causation must be proven within a reasonable medical probability, based upon competent expert testimony, and "[m]ere possibility alone is insufficient to establish a prima facie case." *Jones v. Ortho Pharm. Corp.*, 163 Cal. App. 3d 396, 402 (1985). "A possible cause only becomes 'probable' when, in the absence of other reasonable causal explanations, it becomes more likely than not that the injury was a result of its action." *Id.* at 403. A plaintiff must prove both general causation (here, that Aredia and Zometa have the capacity to cause ONJ) and specific causation (here, that Ms. Messick's ONJ was caused by Aredia or Zometa). *See In re Silicone Gel Breast Implants Products Liab. Litig.*, 318 F. Supp. 2d at 922. Because Ms. Messick bears the ultimate burden of proof on causation, Novartis has only to point to the absence of a genuine issue of material

[1] Novartis contends that there is insufficient evidence establishing causation; that there is no legal or factual showing that Novartis had a duty to warn Ms. Messick; that its warning was adequate; that any warnings would not have been heeded; that strict liability is barred by California law; that there was no express warranty; and that there was no privity of contract. Because this Court finds the causation question dispositive, it expresses no view on the other contentions.

fact to obtain summary judgment. *Daubert II*, 43 F.3d at 1315 (citing *Maffei v. Northern Insulation of New York*, 12 F.3d 892, 899 (9th Cir.1993)).

Novartis argues that if the Court grants its *Daubert* motion to exclude causation testimony by Ms. Messick's experts, then she will have no admissible evidence to prove medical causation, and therefore Novartis would be entitled to judgment as a matter of law on all Ms. Messick's claims. The Court agrees. There is a complete absence of affirmative evidence in the record that Aredia and Zometa more likely than not caused Ms. Messick's ONJ. The Court has excluded specific causation testimony by all of Ms. Messick's experts. Proof that Aredia and Zometa caused Ms. Messick's ONJ is a required element in all her damage claims. Therefore, the Court GRANTS defendant's motion for summary judgment.

CONCLUSION

For the foregoing reasons and for good cause shown, defendant's motion to exclude witness testimony on specific causation is GRANTED. Defendant's motion for summary judgment is GRANTED. (Docket Nos. 20 and 21).

IT IS SO ORDERED.

Dated: February 15, 2013

SUSAN ILLSTON
United States District Judge